

## **REMARKS**

### **I. Background**

The present amendment is in response to the Office Action mailed February 4, 2009. In the present amendment, claims 1-16 have been cancelled, and new claims 17-28 have been added. Thus, claims 17-28 are pending or consideration.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

### **II. Proposed Claim Amendments**

Please amend the claims in the manner indicated above. The new claims are fully supported by the previously pending claims and the specification at least on pages 3-5, Formula II, and the examples. Applicant respectfully asserts that no new matter is added to the application by entry of the new claims.

### **III. Claim Examination**

The cancelled claims 1-16 were drawn to a "use" of a peptide, which the Office Action alleges is improper, and the Examiner indicated the claims were examined as "peptide claims." Applicant respectfully requests the Examiner examine claims under a "method of use" which is more inline with a "use" claim compared to a "peptide claim."

### **III. Claim Objection**

The Office Action objects to claim 7 for an error in the recitation of the peptide. Claim 7 has been cancelled, and the objection is moot.

#### **IV. Rejection Under § 112, Second Paragraph**

The Office Action rejects claims 1-16 under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1-16 have been cancelled and replaced with new claims 17-28, which are drawn to a method for treating shock. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

The Office Action rejects claims 1-6 and 9-14 under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting “moiety.” Applicant respectfully disagrees that moiety is indefinite because it is a term of art that is used repeatedly and consistently to specify a chemical entity. Also, the specification describes moieties sufficiently that the term is not indefinite. In any event, Applicant has removed the term “moiety” from the claims. When referring to an amino acid as a moiety, the term “moiety” has been replaced with “residue.” Applicant contends that from a review of the specification, a skilled artisan would know that the term amino acid “moiety” is an amino acid “residue.”

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

#### **V. Rejection Under § 112, First Paragraph**

The Office Action rejects claims 1-4, 7-12, and 15 under 35 U.S.C. § 112, first paragraph. Claims 1-16 have been cancelled and replaced with new claims 17-28, which are drawn to a method for treating shock. Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

#### **VI. Rejection Under § 101**

The Office Action rejects claims 1-16 under 35 U.S.C. § 101 because the claim recitation of a “use” without setting forth any steps. Claims 1-16 have been cancelled and replaced with new claims 17-28, which are drawn to a method for treating shock. Withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

#### **VII. Rejection Under § 102**

The Office Action rejects claims 1-5 under 35 U.S.C. § 102 as being anticipated by WO 99/02565 (21, Jan. 1999, Therasorb Medizinische Systeme GMBH, hereinafter “the 99/02565 reference”). Applicant respectfully traverses because claims 1-5 have been cancelled, thereby

rendering the rejection moot. Additionally, Applicant respectfully asserts that the 99/02562 reference does not teach each and every element of the presently pending claims 17-28.

Applicant respectfully asserts that the 99/02565 reference does not teach each and every element of the presently pending claims. As such, the 99/02565 reference does not teach the substance of Formula II, as recited in claim 17. Additionally, the 99/02565 reference does not teach any method for treating shock<sup>1</sup>, and thereby cannot teach a method of treating shock by administering the substance of Formula II.

The Office Action rejects claims 1-4, 7-12, and 15-16 under 35 U.S.C. § 102(b) as being anticipated by Dean et al. (WO 93/17719). Applicant respectfully traverses because claims 1-5 have been cancelled, thereby rendering the rejection moot. Additionally, Applicant respectfully asserts that Dean does not teach each and every element of the presently pending claims 17-28.

Applicant respectfully asserts that Dean does not teach each and every element of the presently pending claims. As such, Dean does not teach the substance of Formula II, as recited in claim 17. Additionally, Dean does not teach any method for treating shock, and thereby cannot teach a method of treating shock by administering the substance of Formula II.

The Office Action rejects claims 1-4, 7-12, and 15-16 under 35 U.S.C. § 102(b) as being anticipated by Dean et al. (US 5,720,934, hereinafter “Dean II”). Applicant respectfully traverses because claims 1-5 have been cancelled, thereby rendering the rejection moot. Additionally, Applicant respectfully asserts that Dean II does not teach each and every element of the presently pending claims 17-28.

Applicant respectfully asserts that Dean II does not teach each and every element of the presently pending claims. As such, Dean II does not teach the substance of Formula II, as recited in claim 17. Additionally, Dean II does not teach any method for treating shock, and thereby cannot teach a method of treating shock by administering the substance of Formula II.

The Office Action rejects claims 1-4, 7-12, and 15-16 under 35 U.S.C. § 102(a) or 102(e) as being anticipated by Petzelbauer (US 2004/0192596). Applicant respectfully traverses because

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<sup>1</sup> Applicant reviewed the English translated version, and could not find the term “shock,” and thereby, the 99/02565 reference

claims 1-5 have been cancelled, thereby rendering the rejection moot. Additionally, Applicant respectfully asserts that Petzelbauer does not teach each and every element of the presently pending claims 17-28.

Applicant respectfully asserts that Petzelbauer does not teach each and every element of the presently pending claims. Petzelbauer does not teach any method for treating shock, and thereby cannot teach a method of treating shock by administering the substance of Formula II. Additionally, Petzelbauer does not teach or suggest any method of treatment for any of the conditions recited in claims 23-28.

The Office Action rejects claims 1-4, 7-12, and 15-16 under 35 U.S.C. § 102(a) or 102(e) as being anticipated by Petzelbauer (US 2007/0037749, hereinafter “Petzelbauer II”). Applicant respectfully traverses because claims 1-5 have been cancelled, thereby rendering the rejection moot. Additionally, Applicant respectfully asserts that Petzelbauer II does not teach each and every element of the presently pending claims 17-28.

Applicant respectfully asserts that Petzelbauer II does not teach each and every element of the presently pending claims. Petzelbauer II does not teach any method for treating shock, and thereby cannot teach a method of treating shock by administering the substance of Formula II. Petzelbauer II does not teach or suggest any method of treatment for any of the conditions recited in claims 23-28.

In view of the foregoing remarks regarding the 99/02565 reference, Dean, Dean II, Petzelbauer, and/or Petzelbauer II, none of these references teach each and every element of currently pending claims 17-28. Thus, withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

### **VIII. Double Patenting**

The Office Action rejects claims 1-4, 7-12, and 14-16 under the non-statutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. 7,271,144 (hereinafter, “the ‘144 patent”). Applicant respectfully traverses because the presently claimed invention is not obvious

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cannot teach a method of treating shock. Nothing could be found that linked microcirculation disorders and shock.

under the ‘144 patent because the Office Action has not established a *prima facie* case of obviousness with regard to the ‘144 patent. None of claims 1-4 of the ‘144 patent claim, teach or suggest anything related to stress or methods for treating stress. Since claims 1-4 of the ‘144 patent do not claim, teach, or suggest anything related to treating stress, the currently pending claims are patentably distinct. Thus, the presently claimed invention recited in claims 17-28 is distinct and patentable over the ‘144 patent, and the non-statutory obviousness-type double patenting rejection is improper.

The Office Action rejects claims 1-4, 7-12, and 14-16 under the non-statutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Application 11/542,050 (US 2007/0037749, hereinafter “Petzelbauer II”). Applicant respectfully traverses because the presently claimed invention is not obvious under Petzelbauer II because the Office Action has not established a *prima facie* case of obviousness with regard to Petzelbauer II. None of claims 1-24 of Petzelbauer II claim, teach, or suggest anything related to stress or methods for treating stress. Since claims 1-24 of Petzelbauer II do not claim, teach, or suggest anything related to treating stress, the currently pending claims are patentably distinct. Thus, the presently claimed invention recited in claims 17-28 is distinct and patentable over Petzelbauer II, and the non-statutory obviousness-type double patenting rejection is improper.

The Office Action rejects claims 1-4, 7-12, and 14-16 under the non-statutory obviousness-type double patenting as being unpatentable over claims 8-10, and 14-25 of U.S. Application 11/678535 (US 2008/003938, hereinafter “Petzelbauer III”). None of claims 8-10, and 14-25 of Petzelbauer III claim, teach, or suggest anything related to stress or methods for treating stress. Since claims 1-24 of Petzelbauer III do not claim, teach, or suggest anything related to treating stress, the currently pending claims are patentably distinct. While Petzelbauer III does teach a peptide, the requirements in claims 8-10 and 14-25 of Petzelbauer III for X17 distinguishes said claims to be patentably distinct from the presently claimed invention. Thus, the presently claimed invention recited in claims 17-28 is distinct and patentable over Petzelbauer III, and the non-statutory obviousness-type double patenting rejection is improper.

In view of the foregoing, Applicant submits that the non-statutory obviousness-type double patenting rejections are improper, and withdrawal is respectfully requested.

**IX. Conclusion**

Applicant respectfully asserts that claims 17-28 are patentable over the prior art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to Deposit Account No. 23-3178: (1) any filing fees required under 37 CFR § 1.16; or (2) any patent application and reexamination processing fees under 37 CFR § 1.17.

DATED this 4<sup>th</sup> day of May 2009.

Respectfully submitted,

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